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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,584

04/09/2004

Terrance P. Snutch

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25225 7590 05/14/2009

MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

BLAKELY III, NELSON CLARENCE

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,584	<b>Applicant(s)</b> SNUTCH ET AL.	
	<b>Examiner</b> NELSON C. BLAKELY III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3-5,7-9 and 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6 and 10 is/are rejected.
- 7) ☒ Claim(s) 1,2,6 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/16/2008 and 12/30/2008</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

Claims 1-17 of the instant application are pending. Instant claims 3-5, 7-9 and 11-17 are withdrawn pursuant to Applicant's Amendment, filed 12/30/2008. Accordingly, instant claims 1, 2, 6 and 10 are presented for examination on their merits.

### ***Information Disclosure Statement***

The Information Disclosure Statements, filed 09/16/2008 and 12/30/2008, are acknowledged and considered.

### ***Terminal Disclaimer***

The terminal disclaimer, filed on 12/30/2008, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,949,554; 6,951,862; 6,011,035; 6,294,533; 6,387,897; 6,617,322; 6,943,168; and 7,064,128, or of any patent granted on pending Application Nos. 11/214,218 filed 08/29/2005; 10/928,564 filed 08/27/2004, and 10/821,389 filed 04/09/2004, has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Applicant's Amendments***

Applicant's Preliminary Amendment, filed 01/31/2005, wherein claims 1 and 4-9 are amended, is acknowledged. Applicant's Amendment, filed 12/30/2008, wherein claim 1 is amended, and claims 3-5, 7-9 and 11-17 are withdrawn, is acknowledged.

### ***Specification***

The disclosure is objected to for the following informalities:

On page 14, in Reaction Scheme 4, the unit for degrees "C°" should be replaced with "°C" between steps 21 and 22, and 23 and the final product, respectively.

The use of the trademark CELITE® has been noted in this application, in paragraph [0078], line 3, for example. A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

### ***Claim Objections***

Claims 1, 2, 6 and 10 are objected to for the following informalities:

With respect to instant claim 1, Applicant is encouraged to use superscripts when referring to substituents  $n^1$ - $n^5$ , i.e.,  $n^1$ - $n^5$ , in the structure. See line 16 (text) of claim 1. Additionally, Applicant is encouraged to place the  $R^1$ - $R^5$  substituents in parentheses and to subscript the substituents  $n^1$ - $n^5$ , i.e.,  $(R^1)_x$ , wherein  $x = n^1$ .

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 1, Applicant claims wherein  $R^1$  is independently optionally substituted alkyl (1-10C), i.e.,  $CF_3$ ; however, in claim 2, Applicant claims wherein  $R^1$  is independently optionally substituted alkyl. Claim 2 does not further limit, but rather broadens the limitation of claim 1.

With respect to instant claims 2, 6 and 10, Applicant is encouraged to insert a “, (comma)” after the claim number, i.e., “The method of claim 1, wherein...”.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 2, 6 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of a condition, i.e., pain, does not reasonably provide enablement for the prevention of pain, for example. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As stated in the MPEP § 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present
5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed, and
8. The level of skill in the art

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*The State of the Prior Art and the Predictability or lack thereof in the art*

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It is noted that the Applicant provides a method for the treatment of human and animal subjects using the compounds of the invention formulated as pharmaceutical or veterinary compositions, wherein the type of treatment desired may be prevention or prophylaxis in paragraph [0057] of the instant specification. However, the generally accepted definition of "prevent" is to keep from occurring, or to anticipate. Therefore, by the Examiner's broadest reasonable interpretation of the claims to Applicant's method for preventing a condition, i.e., pain, the "prevention" of said pain lacks enablement due to undue experimentation required to predictably practice the prevention embodiments by Applicant's instant disclosure. Additionally, the art fails to provide compensatory guidance in the prevention of the onset of pain. The Merck Manual [Pain, The Merck Manual of Diagnosis and Therapy (17<sup>th</sup> Edition), pages 1363; 1999] discloses that several pain syndromes are difficult to classify, and that in most patients, chronic headache may involve a complex interaction of nociceptive disturbances in muscles and in blood vessels with psychologic factors. Thus, since neither the instant specification, nor the prior or current art provides sufficient guidance as to how the instantly claimed method could be used to prevent pain, it would require undue experimentation to practice the invention as broadly claimed. Additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing pain, which is seen to be lacking a clear description via art recognized procedural and methodological steps.

*The Amount of Direction or Guidance Present and Presence or Absence of Working*

*Examples*

There is no data present in the specification for the “prevention” pain. The specification only discloses in paragraph [0057], for example, that the compound of formula (1) may be used for treatment of pain, wherein the type of treatment desired may include prevention and prophylaxis. The guidance in the specification is limited to the disclosure that the compound treats pain; however, it is not discussed that said compound can prevent pain.

*The Breadth of the Claims*

The instant breadth of the rejected claims is broader than the disclosure; specifically, the instant claims include “prevention” of *any* pain.

*The Quantity of Experimentation Needed and the Level of Skill in the Art*

While the level of skill in the pharmaceutical arts is high, it would require undue experimentation for one of ordinary skill in the pertinent art to prevent *any* pain. The science of drug development has evolved such that, without guidance or working examples in the specification, the claims lack enablement.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614  
May 8, 2009

/N. C. B. III/  
Examiner, Art Unit 1614